DEVICE DESCRIPTION

The WALLSTENT® Venous Endoprosthesis is comprised of two components: the implantable metallic stent and the UNISTEP™ Plus Delivery System.

- The stent is composed of biomedical superalloy wire with a radiopaque core braided in a tubular mesh configuration.
- The delivery system is composed of co-axial tubes which allow reconstrainment as indicated by the limit marker and has radiopaque marker bands which aid in accurate placement of the stent.

The Wallstent® Venous Endoprosthesis is available in the following diameters: 10, 12, 14, 16 mm. See Table 1 for stent sizing information.

Stent diameter selected should be approximately 1 mm to 2 mm larger than the vessel diameter desired. Deployed lengths reflect expansion to desired vessel diameter. Constricting the stent to a smaller diameter will cause a longer deployed length, depending on the degree of constriction. On average, a 0.5 mm change in diameter yields a 10-15% change in length. Once the desired vessel diameter is reached, no additional reduction in stent length should occur.

Table 1: Stent Sizing Specifications

WALLSTENT® Venous Endoprosthesis
Vessel Diameter and Approximate Implanted Stent Length

	Fully Opened Stent Diameter / Length		WALLSTENT® Venous Endoprosthesis When Implanted in Specified Vessel Diameter			
Order Number	Diam. (mm)	Length (mm)	Vessel Diam. (mm)	Stent Length (mm)	Vessel Diam. (mm)	Stent Length (mm)
71-132	10	20	8	33	9	27
71-134	10	42	8	54	9	48
71-136	10	68	8	77	9	69
71-138	10	94	8	115	9	103
40210	12	20	10	31	11	26
40211	12	40	10	51	11	47
40212	12	60	10	73	11	66
40213	12	90	10	110	11	100
40310	14	20	12	33	13	27
40311	14	40	12	50	13	46
40312	14	60	12	72	13	65
40313	14	90	12	107	13	98
40330	16	20	14	28	15	23
40331	16	40	14	49	15	45
40332	16	60	14	70	15	64
40333	16	90	14	105	15	97

MRI Safe: The WALLSTENT Self-Expanding Stent has shown no deflection or torque in the area of maximum spatial gradient (450 gauss centimeter) of a 1.5 tesla MRI system under conditions that produced a Specific Absorption Rate (SAR) of 1.3 W/Kg. Imaging artifacts affect the region of interest at the location of the device (artifact ration 0.8 to 7.0), while areas away from the device appear unaffected by their presence.

INDICATIONS

The WALLSTENT® Venous Endoprosthesis is indicated for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract. Unsuccessful angioplasty is defined as residual stenosis ≥ 30% for a vein ≤ 10 mm in diameter or ≥ 50% for a vein > 10 mm in diameter, a tear which interrupts the integrity of the intima or lumen, abrupt lesion site occlusion, or refractory spasm. The vessels that can be treated with the WALLSTENT® Venous Endoprosthesis are the innominate and subclavian veins, ranging from 8 mm to 15 mm in diameter.

CONTRAINDICATIONS

The WALLSTENT® Venous Endoprosthesis is contraindicated for use in: patients with bleeding disorders unresponsive to vitamin K or blood product therapy.

WARNINGS AND PRECAUTIONS

Warnings

- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Subsequent restenosis may require repeat dilation of the vessel segment containing the stent. The long-term outcome following repeat dilation of venous stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.
- Proper stent sizing is critical to achieving adequate vessel apposition and avoiding possible stent migration. Refer to Table 1 for sizing information.

Reuse Precaution Statement

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.
- For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

Stent Handling Precautions

- Store in a dry, dark, cool place.
- Do not use opened or damaged packages.

- Do not expose delivery catheter to organic solvents, e.g., isopropyl alcohol. Such an exposure can cause delivery catheter to become brittle.

Stent Placement Precautions

- The target lesion should be predilated with a conventional balloon angioplasty catheter prior to stent placement.
- Do not release the stent if unusual force is required. If the stent does not deploy easily, use another device.
- Do not advance the delivery catheter without the guide wire extending from the tip.
- Do not fully deploy the stent if it is not properly positioned in the vessel.
- Do not advance a partially (≤ 50%) deployed stent. Reconstrain and then move distally. Partially deployed stents can be pulled proximally, if necessary.
- Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see Step 10 in the Procedure Section.
- A stent cannot be repositioned after the deployment threshold has been exceeded.
- Implanting a stent may lead to dissection of the vessel distally, and/or proximally, to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., surgery, further dilation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by the stenting of the more proximal lesion(s). Stenting in this order obviates the need to cross the proximal stent in the placement of the distal stent and reduces the chance for dislodging the proximal stent.
- Stenting across a major side branch could obstruct the side branch and prevent or hinder percutaneous access or future interventions.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular site. Complications can include bleeding, hematoma or pseudoaneurysm.

Stent/System Removal Precautions

- If Stent/System removal is required prior to full deployment, and when the stent is ≤50% deployed, first attempt to reconstrain the stent and remove as described in number 8 of the Procedure Section. If the stent cannot be reconstrained, remove the entire Stent/System as follows: Hold the T-connector securely on the stainless steel tube and cautiously withdraw the Stent/System back toward and into the introducer sheath. The delivery system and

introducer sheath can then be removed, with the guidewire left in place.

- Failure to follow these steps could potentially result in loss of, or damage to, the stent or delivery system.

Post Implant Precautions

- Care must be exercised when crossing a newly deployed stent with intravascular ultrasound (IVUS), or a guide wire, or a balloon catheter to avoid disrupting the stent geometry.

- Be aware of the location of stented venous lesions. Dislodging stents with catheters or other transluminal devices may produce unexpected stent migration.

ADVERSE EVENTS

Observed Adverse Events

A total of 42 patients were enrolled in the multi-center study of Wallstent Venous Endoprosthesis for central lesions. This study was conducted at 12 investigational sites.

Patients from the Wallstent® Venous Endoprosthesis study form the basis of the observed events described in **Table 2**.

Five (5) patients enrolled in the Wallstent® Venous Study died during the trial. None of these deaths occurred in the first 6 months following the Wallstent procedure and none were considered device related. The cause of death was reported as follows: (1) hyperkalemia 475 days post procedure; (2 and 3) cardiac arrest at 343 and 631 days post procedure; (4) septicemia with peripheral vascular disease and gangrene 902 days post procedure; (5) stomach cancer 276 days post procedure.

Table 2 Safety Results, Wallstent Venous Central Patients (N=42)		
Adverse Event	**Result**	**95% C.I.**
General Events		
Death	11.9% (5/42)	[4.0%, 25.6%]
Surgical Revision	4.8% (2/42)	[0.6%, 16.2%]
Access abandoned from central lesion	40.5% (17/42)	[25.6%, 56.7%]
Access abandoned from peripheral graft	21.4% (9/42)	[10.3%, 36.8%]
Non-Stent-Related Events		
Graft Occlusion/Restenosis	45.2% (19/42)	[29.8%, 61.3%]
Pseudoanuerysm	16.7% (7/42)	[7.0%, 31.4%]
Infection	14.3% (6/42)	[5.4%, 28.5%]
Hematoma	4.8% (2/42)	[0.6%, 16.2%]
Stent-Related Events		
Stent Restenosis	76.2% (32/42)	[60.5%, 87.9%]
Stent Thrombosis	50.0% (21/42)	[34.2%, 65.8%]
Migration	2.4% (1/42)	[0.1%, 12.6%]
Edema	40.5% (17/42)	[25.6%, 56.7%]

Results are percent (count/sample size) of all patients experiencing the event, and reflect each patient's entire study experience regardless of length of follow-up.

Mean ± SD (sample size) (min, max) length of follow-up in days; 350.5±299.4 (42) (4.0.1434). Confidence intervals are based on exact limits.

Note: Surgical revision refers to those events where the graft was revised, but not abandoned. Patients reporting edema are a subset of patients with stent restenosis/thrombosis.

Additional clinical safety data were retrospectively obtained on 12 patients enrolled in a physician's registry study of the Wallstent Venous Endoprosthesis for the treatment of stenotic or occluded subclavian veins of patients undergoing hemodialysis. Four deaths were reported among these 12 patients. The reported cause and time of occurrence of these deaths is: sepsis at 16 days post-procedure, aspiration pneumonia at 32 days post-procedure, myocardial infarction/subdural hematoma at 81 days post-procedure, and hypotension at 240 days post procedure.

Adverse events related to either the stent or the stent implant procedure included stent thrombosis (5), stent restenosis (8), stent migration (3), and an allergic reaction to contrast media (1). The three stent migrations in this physician single-center study and the one stent migration in the multi-center Wallstent Venous central lesion study were attributed to incorrect sizing of the stent and/or dislodgment with the guide catheter. All of the stent migration cases were treated with a percutaneous procedure and none resulted in abandonment of the access site.

Potential Adverse Events

Potential adverse events associated with use of the WALLSTENT® Venous Endoprosthesis may include the usual adverse events reported for conventional percutaneous transluminal angioplasty such as: hemorrhage, infection, contrast media reactions, dissection, distal emboli, graft rupture, graft/vein thrombosis or occlusion, perforation of the vein, suture disruption of the anastomosis, thromboembolism or transient spasm.

Potential adverse events associated with the WALLSTENT® Venous Endoprosthesis are stent misplacement, stent migration, or vein perforation.

Observed Device Malfunctions

Two incidents of stent malfunction were reported in the central venous lesion study. In one incident, the delivery system failed to deploy. In the second incident, the stent did not fully expand.

CLINICAL STUDIES

A total of 42 patients at 12 investigational sites within the United States were enrolled in a prospective, multi-center, non-randomized study with a historical percutaneous transluminal angioplasty (PTA) control cohort to investigate the safety and efficacy of the Wallstent Venous Endoprosthesis for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis.

Primary Endpoint: The primary endpoint for the Wallstent Venous trial was *circuit secondary patency* at 6 months. **Circuit Secondary Patency** is defined as the proportion of patients, over time, that have an occluded vessel that is successfully opened. Failure of circuit secondary patency occurs at the time the dialysis site is abandoned due to the inability to treat the stenosis, or occlusion of either the central lesion under consideration or any other peripheral or *de novo* central lesion.

Other endpoints evaluated include:

Stent Primary Patency, defined as the proportion of patients, over time, that have had uninterrupted (intervention-free) patency since the initial procedure. Primary patency ends at the first occurrence of one of the following: initial re-intervention for the purpose of treating patency of the central lesion; anatomical failure (50% or greater stenosis) of the central lesion; or when the dialysis site is abandoned due to the inability to treat the original central lesion. If percent stenosis of the central lesion is undetermined, the occurrence of arm/face edema indicates the end of primary patency.

Stent Secondary Patency, defined as the time to failure of the access site due to stenosis or occlusion of the stented central lesion. Anatomical failure (>50% stenosis) of the central lesion which is not successfully reopened is also considered failure of stent secondary patency. Patients failing circuit secondary patency due to other peripheral lesions, problems at the access site (e.g. pseudoaneurysm, infection), or a *de novo* central lesion that does not involve the stent margin, do not fail stent secondary patency. These patients are censored from analysis

at the date of the last follow-up documenting patency of the stent.

Patency rates were estimated by means of Kaplan-Meier Survival Analysis.

Patient Eligibility: Patients were eligible for the study if they were on chronic hemodialysis and had a central venous stenosis which was treatable with PTA. If the PTA failed to reduce the stenosis to less than 50% in patients with a vein >10 mm in diameter, or 30% in a vein ≤10 mm in diameter, the patient received a WALLSTENT® Venous Endoprosthesis. If the PTA was successful, but the stenosis recurred within 4 months, the patient received a WALLSTENT® Venous Endoprosthesis.

Study Methods: Clinical follow-up was obtained at 1 week, 2 months, 6 months, and every 6 months thereafter until study conclusion, or the graft site was abandoned. Baseline quantitative angiography was performed pre-procedure, following balloon angioplasty, following device deployment, and at the 2-month and 6-month visit. The stent primary patency, stent secondary patency, and circuit secondary patency were analyzed.

Results: Among the 42 patients enrolled in the study, lesions involved the innominate vein in 14, subclavian vein in 23, and both subclavian and innominate veins in 5 patients. The mean lesion length was 25.8mm (±18.8, range = 2.0-81.6mm). Multiple stents were implanted in 5 patients (11.9%). A total of 28.6% of the patients (12/42) had occluded (100% stenoses) veins at the time of the study enrollment.

Initial intraoperative success, as measured by the reduction in stenosis to ≤30%, or angiographic demonstration of an increase in venous outflow, was achieved in 100% of patients. Analysis of the clinical data demonstrated a 74.3% circuit secondary patency rate at six months for the WALLSTENT® study group, compared to a 50% secondary patency rate for the historical control of percutaneous transluminal angioplasty (PTA), resulting in a highly significant statistical difference ($p<0.0003$). The WALLSTENT® Venous Endoprosthesis was found to provide superior efficacy in the central venous patient cohort when compared to the historical control (PTA).

Baseline demographic and lesion characteristics were individually regressed on time to loss of circuit secondary patency to assess possible predictors of clinical outcome (univariate analysis). Presence of an occluded lesion pre-procedure was significantly associated with circuit secondary patency ($p=0.022$). The same variables were analyzed using stepwise selection to identify a multivariate predictor model. Presence of a totally occluded lesion pre-procedure was the only variable associated with time to loss of circuit secondary patency ($p=0.0072$). Implantation of multiple stents approached significance in the multivariate model ($p=0.062$).

Principal Efficacy and Safety results are summarized in Table 3.

Table 3. Principal Efficacy and Safety Results, BSC Patients (N=42)

Efficacy Measures	Result	95% C.I.
Device Success	100.0% (42/42)	[91.6%,100.0%]
Initial Intraoperative Success:		
Criterion 1: ≤30% Residual Stenosis	64.3% (27/42)	[48.0%,78.4%]
Criterion 2: Increased Venous Flow	90.5% (38/42)	[77.4%,97.3%]
Met Either Criteria	100.0% (42/42)	[91.6%,100.0%]
Acute Procedure Success	64.3% (27/42)	[48.0%,78.4%]
Initial Clinical Success	95.8% (23/24)	[78.9%,99.9%]
Pre-PTA RVD (mm)	12.6±3.7 (42) (3.0,20.1)	[11.5,13.7]
Post-Stent MLD (mm)	8.8±2.8 (39) (3.7,20.2)	[7.9,9.7]
Post-Stent %DS	24.1±18.4 (42) (0.0,63.0)	[18.5,29.6]
6-Month RVD (mm)	10.4±3.3 (25) (4.0,18.3)	[9.1,11.7]
6-Month MLD (mm)	3.0±2.7 (26) (0.0,11.0)	[1.9,4.0]
6-Month %DS	67.9±29.1 (26) (9.0,100.0)	[56.7,79.1]
Patency		
6-Month Stent Primary Patency (K-M)	24.4%	[9.8%,39.0%]
6-Month Stent Secondary Patency (K-M)	82.5%	[69.7%,95.2%]
6-Month Circuit Secondary Patency (K-M)	74.3%	[60.6%,88.1%]
Stent Restenosis	76.2% (32/42)	[60.5%,87.9%]
Arm-Face Edema	40.5% (17/42)	[25.6%,56.7%]
Safety Measures	**Result**	**95% C.I.**
Major In-Hospital Event	0.0% (0/42)	[0.0%,8.4%]
Out-of-Hospital (Stent-Related) Event		
Stent Thrombosis	50.0% (21/42)	[34.2%,65.8%]
Migration	2.4% (1/42)	[0.1%,12.6%]
Death	11.9% (5/42)	[4.0%,25.6%]

Results are mean ± SD (sample size) (min, max) for continuous variables, and percent (count/sample size) for binary variables.
Confidence intervals for binomial proportions are based on exact limits.
Patency rates are Kaplan-Meier estimates at 180 days; confidence intervals based on Greenwood standard errors.
RVD = Reference Vessel Diameter.
MLD = Minimum Lumen Diameter.
%DS = percent diameter stenosis which refers to "within lesion" measurement technique.
Device Success = Stent(s) deployed completely.
Initial Intraoperative Success, Criterion 2 = angiographic demonstration of an increase in venous outflow (visualization of less collateral flow, more rapid rate of contrast media clearing or less reflux flow post-procedure).
Acute Procedure Success = ≤30% residual stenosis and absence of major in-hospital event.
Initial Clinical Success = <20% recirculation fraction one week post-procedure. (Note: incomplete number of assessments (N=24) reflects a change in clinical practice during the course of the study in which many institutions stopped using recirculation fractions to monitor patients.)
Stent Restenosis = within stent %DS of 50% or greater, or in the absence of angiography, the presence of arm-face edema.
Stent Thrombosis = total thrombotic stent occlusion documented by angiography. (Note: Stent Thrombosis is a subset of stent restenosis).

Additional clinical efficacy data was also retrospectively obtained on 12 patients enrolled in a physician's registry study of the Wallstent Venous Endoprosthesis for the treatment of stenotic or occluded subclavian veins of patients undergoing hemodialysis. The enrollment criteria for this study were similar to the multi center Wallstent Venous central lesion study . A Kaplan-Meier Survival analysis estimated the six-month circuit secondary patency, stent primary patency, and stent secondary patency rates at 68.6%, 33.8%, and 75%, respectively, for this patient cohort.

PATIENT SELECTION AND TREATMENT

Individualization of Treatment

The risks and benefits of using the WALLSTENT Venous Endoprosthesis should be carefully considered for each patient before use. Stenting is generally avoided in those patients at heightened risk of bleeding (e.g., bleeding disorders unresponsive to Vitamin K or blood product therapy, see Contraindications.)

Premorbid conditions that increase the risk of a poor initial result should also be considered. The relationship of baseline and procedural variables to failure of circuit secondary patency was examined. Presence of an occluded lesion pre-procedure was the only statistically significant predictor for failure of circuit secondary patency. Implantation of multiple stents approached significance in one analysis.

Use in Special Population

The safety and effectiveness of the WALLSTENT Venous Endoprostheis have not been established for the following:

- Veins that are smaller than 8.0 mm or larger than 15 mm.
- Where stenting would not allow for sufficient puncture sites of the hemodialysis access.
- Where damage to a diseased or injured vessel may occur due to the self-expanding nature of the stent.
- Veins other than the innominate or subclavian.
- Lesions at or within 5 mm of the arterial anastomosis.
- When significant intraluminal thrombus is present after thrombolytic therapy.
- Multiple lesions greater than 4 cm apart.
- Patients for longer than 6 months.

HOW SUPPLIED

Contents

- One (1) WALLSTENT Venous Endoprosthesis with Unistep Plus Delivery System
- One (1) Instructions For Use Manual
- One (1) Stent Implant Card

PREPARATION OF THE DELIVERY SYSTEM FOR INSERTION

1. Recommended Material For Implant:

- Prepare the following material using sterile technique:
- 10 cc syringe filled with sterile saline.
- 6F hemostatic introducing sheath, approximately 10-12 cm long, for the 6F delivery system.
- 7F hemostatic introducing sheath, approximately 10-12 cm long, for the 7F delivery system.
- 8F hemostatic introducing sheath, approximately 10-12 cm long, for the 8F delivery system.
- 9F hemostatic introducing sheath, approximately 10-12 cm long, for the 9F delivery system.
- 180 cm exchange length, 0.035" or 0.038" guide wire.

2. Length Selection

Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant. After considering the desired implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. (See Table 1.) Should two stents be required to cover the lesion, place the distal stent first, followed by the proximal stent, and allow for generous overlapping. Deployed lengths reflect expansion to desired vessel diameter. Constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.

3. Initial Preparation Of Instrument:

- Carefully remove the delivery system from its protective packaging.
- Visually inspect the entire device for damage or defects.
- Visually check that the leading end of the stent is covered by the exterior tube.
- Ensure that no stent wires have perforated the exterior tube.

4. Flushing The Delivery System:

- Attach a 10 cc syringe filled with sterile saline to the stopcock on the extension tube.
- Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
- After priming the delivery system, close the stopcock and remove the syringe.
- Verify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved towards the trailing end, exposing stent wires. Proper device function cannot be assured during implant, and such use may cause vessel injury.

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PROCEDURE

1. Use radiopaque marker bands to identify the area to be dilated and stented.
2. Place a 0.035" exchange guidewire percutaneously into the vessel to be treated.
3. Dilate the venous lesion with a balloon catheter measuring 10-20% less than the nominal stent diameter, using accepted technique and protocol.
4. Remove the balloon catheter, leaving the guidewire in place.
5. Having prepared the delivery system as previously described, insert the delivery system into the appropriate size introducer sheath and over the guidewire.

   NOTE: Always use an introducer sheath for the implant procedure, to protect the puncture site, in the event a partially deployed stent were to be removed.

6. Guidelines for stent positioning:

- Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.
- The radiopaque marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary.
- Maintain the delivery system as straight as possible during deployment of the stent.

7. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.

   PRECAUTION: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see Step 10.

8. Assess stent position and reposition if desired. To reposition, reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. It may be necessary to guide the delivery system into the introducer sheath. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

NOTE: To facilitate reconstrainment, the delivery system may be flushed with heparinized saline.

9. To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

   PRECAUTION: A stent cannot be repositioned after the deployment threshold has been exceeded.

10. To remove a partially deployed stent, first reconstrain the stent (see Step 8). If the stent cannot be reconstrained, remove the entire Stent/System as follows: Hold the T-connector securely on the stainless steel tube and cautiously withdraw the Stent/System back toward and into the introducer sheath. The entire delivery system can be pulled into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.

    As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

11. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed. If desired, repeat balloon dilation inside the implanted stent may be performed to achieve nominal stent diameter. For this procedure, a new balloon dilatation catheter is recommended.

12. Using standard operative procedures, perform routine venography to demonstrate location and patency of the stent.

13. The implanted stent length should allow for adequate overlapping into the non-strictured vessel to compensate for further stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.

    If, prior to initial stent implantation, it is expected that a second stent will be necessary to cover the lesion, cover the distal end of the lesion with the first stent and use the second stent to cover the proximal portion of the lesion. This will minimize interference with placement of the second stent by the previously deployed stent.

14. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery system.

PATIENT INFORMATION

Physicians will be provided, separately, copies of a Patient Guide that includes information on venous stenosis, the Wallstent Venous Endoprosthesis, and the stent implant procedure.